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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,445	06/11/2001	Gregory R. Mundy	OSTS:003USD2	4570
7590	12/03/2004		EXAMINER HOLLERAN, ANNE L	
Steven L. Highlander, Esq. FULBRIGHT & JAWORSKI L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			ART UNIT 1642	PAPER NUMBER
DATE MAILED: 12/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,445

Applicant(s)

MUNDY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed July 7, 2004 is acknowledged. However, in view of newly discovered references, the finality of the previous Office action is withdrawn and prosecution on the merits continues.

2. Claim 25 was amended. Claim 27 was canceled. Claims 25, 30 and 31 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections Withdrawn:

4. The rejection of claims 25, 30 and 31 under 35 U.S.C. 102(b) as being anticipated by Suda (U.S. Patent 4,391,802; issued July 5, 1983) as evidenced by Falzon (Falzon, M. et al. Endocrinology, 139(3): 1046-1053, 1998) is withdrawn in view of the amendment to claim 25.

New Grounds of Rejection:

5. Claims 25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Liliemark (Liliemark, J., et al, Leukemia and Lymphoma, 4: 271-276, 1991).

The claimed inventions are drawn to methods comprising the step of administering to a cancer patient a compound that is OSW3 or OSW6. The specification teaches that OSW6 is 6-

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thioguanine (page 8, description of Figure 5). The administration may be repeated, and the administration route may be oral or intravenous.

Liliemark teaches that 6-thioguanine (6-TG) is used in the treatment of acute myelogenous leukemia (AML) and acute lymphoblastic leukemia (page 272, first column.) Liliemark also teaches a method of administering to cancer patients having AML an oral dose of 40 mg (page 272, 2nd column). Thus, Liliemark teaches the claimed methods.

6. Claims 25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Liliemark (Liliemark, et al, Leukemia and Lymphoma, 4: 271-276, 1991) as evidenced by Hotte (Hotte, S. J., et al., Am. J. Cancer 1(3): 179-187, 2002).

The claimed inventions also read on methods where the cancer patient is suffering from a cancer that metastasized to bone and causes hypercalcemia. As discussed above, Liliemark teaches that 6-thioguanine (6-TG) is used in the treatment of acute myelogenous leukemia (AML) and acute lymphoblastic leukemia (page 272, first column.) As evidenced by Hotte, patients with leukemias and lymphomas have a 4.1 to 4.3 % probability of developing hypercalcemia (page 179, 2nd col. – page 180, 1st column, bridging paragraph). Therefore, Liliemark, as evidenced by Hotte, teaches the claimed methods.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
November 30, 2004


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
12/01/2004